ANNOUNCEMENT OF DRAFT PROJECT REQUIREMENT

Title: Bioinformatics Integration Support Contract (BISC))

Reference Number: NIH-NIAID-DAIT-02-16

Purpose of Announcement

The purpose of this announcement is two-fold: first, to inform potentially interested individuals, institutions and organizations of a draft project requirement of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), designed to establish a Bioinformatics Integration Support Contract, and second, to solicit comments from interested parties with respect to the scope, design and requirements of this draft solicitation.

Please note that proposals are not being solicited at this time. With this announcement, the NIAID is soliciting comments and recommendations on the entire draft project requirement (i.e., Statement of Work, Technical Evaluation Criteria, and Reporting Requirements) in order to: (1) determine interest in this solicitation; (2) assure that requirements included in the documentation will meet the intent of the solicitation; and very importantly, (3) identify or clarify what may appear to be problems, conflicts, or obstacles for an institution or organization that might otherwise wish to become a potential offeror.

It is anticipated that one (1) cost-reimbursement contract will be awarded for a period of seven (7) years. As provided for by FAR.5.205 entitled "Special Situations," a draft project requirement is being broadcast.

We encourage you to respond to Cyndie Cotter, NIAID Contracting Officer, on this matter, using the Response Guidelines provided at the end of the Announcement, to indicate issues or elements you are particularly in favor of, or which you find problematic to the response capacity of your institution or organization. Responses should be submitted by May 15, 2001.

Please note that the Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited. Although "proposal" and "offeror" are used in this Announcement, your response will be treated as information only. It shall not be used as a proposal.

Background and Major Components of the Draft Project Requirement

This solicitation is focused on large-scale data basing and analysis in research areas critical to the NIAID. Tremendous growth of scientific information (much rooted in genome-oriented research) has created the need for this initiative for several reasons, including: (a) the need for technical assistance to multiple research programs which lack sufficient bioinformatics guidance and support, especially where new genomic

technologies are concerned; (b) the need for a shared data resource and introduction of special data handling capability; and, (c) the need to foster standards of practice in life science discovery by supporting advances in data collection, curation, and exchange which can be adapted by various NIAID divisions, as well as other NIH institutes.

The purpose of this initiative is to provide information technology support in the production, analysis, curation, archiving, and exchange of genomic data, as well as other basic scientific and clinical data. The resulting contract will support a diverse community of NIAID-funded clinical and basic researchers, engaged in a wide range of research activities. It will enable scientists to easily access, generate and exchange complex data sets of high quality with the assurance that these data are portable, interoperable, and survivable over time.

The resulting contract will establish and maintain connectivity, databases, and comprehensive information technology support services to meet the needs of several established and new programs of the NIAID's Division of Allergy, Immunology, and Transplantation (DAIT), including: the Autoimmune Centers of Excellence (ACE, 1999), the Immune Tolerance Network (ITN, 1999), the Inner-City Asthma Consortium (ICAC, 2002), the International Histocompatibility Working Group (IHWG, 2000), the Cooperative Clinical Trails in Pediatric Renal Transplantation Program (PRTP, 1999), and, the Clinical Trials of Stem Cell Transplantation for the Treatment of Autoimmune Disease (SCT/TAD, 2000). Services to be performed by a competitively selected contractor include: (a) conducting a requirements assessment of bioinformatics needs in the targeted programs; (b) designing, implementing and maintaining a data warehouse of genomic and other related data relevant to the research of these programs; (c) providing technical assistance to participating centers in the selection of technologies for the capture, storage, query, and analysis of these data; and, (d) measuring performance and benefits resulting from these technical support activities and planning for their appropriate use in the future. Once established, this platform may be extended to include additional types of data and analyses.

RESPONSE GUIDELINES

BIOINFORMATICS INTEGRATION SUPPORT CONTRACT

REFERENCE NUMBER: NIH-NIAID-DAIT-02-16

Whether you review this draft project requirement as a potential future offeror or as a fact-finding exercise, the NIAID is interested in your feedback. The NIAID is actively soliciting input from academic and industry sources to improve and refine this draft requirement and is seeking to gauge the degree of interest in this effort. PROPOSALS ARE NOT BEING SOLICITED AT THIS TIME. Candid questions and concerns elicited by this notice are encouraged. Comments may address the draft work statement, the technical evaluation criteria, and/or the reporting requirements. Please note that the Government will not provide individual responses to questions/inquiries. However, the extent to which a dialogue may be established with any individual or business entity concerning a given issue raised by this notice shall, for purposes of fairness and compliance with Agency regulations, be determined by the NIAID Contracting Officer after consultation with the cognizant NIAID Technical Program Office.

Examples of feedback may include, but are not limited to:

1. Level of interest in pursuing a prime contract with the NIAID, or a subcontract, consultant or other collaborative relationship with a potential prime contractor, for this requirement. If there is no interest at this time, please explain why.

2. Comments, questions and/or concerns regarding the scope and/or design of the Bioinformatics Integration Support Contract.

Responses should be clear and succinct. We do not desire the submission of any technical or cost proposals. Any critique of the draft project requirement should adequately describe concerns and offer recommendations and/or solutions, which might be used by the NIAID in refining the requirement. Critical technical concerns should be supported with questions posed in such a way as to point toward possible alternatives that may be pursued by the NIAID in refining some aspect(s) of the requirement.

Responses should be submitted by **May 15, 2001**. All responses should include the name, position/title, telephone/extension, facsimile number(s), and electronic mail address(es) of the contact individual. The response should also identify the institution, organization, company, etc., and the complete street address (including, where applicable, location identifiers, e.g., office stop and room number) including zip code.

All response information should be directed in writing by U.S. mail or electronic mail to:

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Attention: Cyndie Cotter, Contracting Officer
Contract Management Branch (Ref. NIH-NIAID-DAIT-02-16)
Division of Extramural Affairs, NIAID
National Institutes of Health
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DRAFT PROJECT REQUIREMENT

REFERENCE NUMBER: NIH-NIAID-DAIT-02-16

TITLE: BIOINFORMATICS INTEGRATION SUPPORT CONTRACT (BISC)

INTRODUCTION

To address the present and future needs of the Government, the Division of Allergy, Immunology and Transplantation (DAIT), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), is seeking a contractor to establish and manage a Bioinformatics Integration Support Contract (BISC) to provide support for several major research programs, including the Autoimmune Centers of Excellence, Immune Tolerance Network, Inner-City Asthma Consortium, International Histocompatibility Working Group, Cooperative Clinical Trails in Pediatric Renal Transplantation Program, and Clinical Trials of Stem Cell Transplantation for the Treatment of Autoimmune Disease. These programs (a) conduct basic scientific research into the genetic correlates of immune disease; (b) design and conduct clinical trials to evaluate the safety, toxicity, and efficacy of immune diseases; and (c) design and conduct studies of the underlying mechanisms of therapeutic agents that are investigated in DAIT clinical trials.

The purpose of this seven-year contract is to provide advanced information technology support in the production, analysis, archiving, and exchange of scientific data for a diverse community of life science researchers by: (a) conducting a requirements assessment of bioinformatics needs in the targeted centers; (b) designing, implementing and maintaining a data warehouse of genomic data relevant to the research of these centers; (c) developing special applications for the collection, storage, and query of these data; (d) providing technical assistance to participating centers in the selection of technologies for the capture, storage, query, and analysis of life science data; and (e) measuring performance and benefits resulting from these technical support activities and planning for their appropriate use in the future.

BACKGROUND

Together with genomics, proteomics, and various other advanced technologies, bioinformatics is enabling life science researchers to greatly deepen our understanding of the immune response. This work promises tremendous insights into the underlying mechanisms and clinical aspects of immune-mediated diseases. If the scientific community continues at the current or a greater rate of productivity, soon we will come to better understand such matters as: (a) genetic and protein pathways in inflammatory responses as determined by cytokines and chemokines; (b) mechanisms of antigen processing and presentation (e.g., proteases, transport molecules, molecules involved in peptide loading, lysosome/endosome function); (c) basic pathways in the maintenance or

disruption of immune tolerance (e.g., T-cell activation factors involved in TCR and co-stimulatory molecule signaling pathways); as well as the role of effector T cells in generation of Th1/Th2 phenotypes, cytotoxic T cell function, function/activation of regulatory T cell subsets, and memory T cell generation. In the future even more than in the past, this work of discovery will depend upon advanced computer support for the collection, storage, and analysis of data.

The need for data integration is broad-based and growing in the life sciences research community. David Roos (Science, February 16, 2001: 1260-1261) observed recently that scientists are awash in a sea of data where they "depend absolutely on accessing data from diverse sources, and being able to integrate, transform, reproduce these data in new formats." The constituent parts of the data integration requirement have been succinctly documented by Spengler (Science, August 17, 2000: 1221-1222) as the following needs: (a) to control the quality of scientific data inputs, (b) to overcome limitations in computer processing capacity for certain complex analytical tasks, (c) to develop quick easy ways to transfer vast amounts of data, and (d) to better automate the search, analysis and normalization of scientific data. Spengler also notes that issues of standards, intellectual property, and long-term sustainability of databases require the attention of scientists, managers, and policy makers.

Activity is underway on many fronts to address these issues. First, recognizing that sequencing efforts to date have provided a "genetics 'parts list" which is not yet sufficient to understand essential aspects of biological function, Brasma, et al (Nature, 17 February 2000: 403, 699-700) propose the expansion of publicly-supported repositories. They also call for the scientific community to jointly develop (a) essential minimum information sets for experimental records, i.e. microarray, (b) shared definitions of ontologies and structured vocabularies, and (c) new tools for searching and executing sophisticated queries of databases containing experimental documents. Second, having anticipated some of the emerging data integration requirements, some labs and clinics have piloted data integration projects. Yet, despite some impressive results on a small scale, there is no certainty that these solutions will be widely adopted or that they will scale to meet the needs of larger, more diverse research communities over greatly extended time periods. In depicting salient trends regarding data exchange standards, finally, Achard, Vaysseiz, and Barillot (Bioinformatics, v. 17, no. 2, 2001, p. 115-125) have noted the partial diffusion of emerging standards in the life science research community. If it continues, this trend may enhance discovery by greatly enabling data sharing.

The solicitation guidelines provided herein represent the NIAID's best effort to address the current situation. They are motivated by recognition that certain kinds of scientific progress are only possible if we ensure the integrity, usability, survivability, and interoperability of life science data now being collected. This solicitation is further motivated by a recognition that recent technological advances in information technology offer unprecedented opportunities for data integration and sharing which can greatly benefit life science discovery.

With the current situation in mind, this contract aims to facilitate the broad diffusion of practices, methods, systems, and tools that serve the needs of its various, diverse communities. It is envisioned that the needs of the NIAID's research community will be well served by (a) establishing a central data archive linking lab and clinical data, (b) construction, documentation, and maintenance of a data-model, as well as necessary vocabularies and ontologies to make the archive useable by a diverse research community, (c) integrating data and applications from existing archives and data resources, and, (d) providing access to researchers and other end-users according to precisely-defined research protocols and strictly enforced provisions for the protection of human subjects. This contract will bring together large heterogeneous data sets and enable complex analyses. It will be an actively curated resource serving both clinical and basic researchers. It will support collaboration and advanced bio-statistical analysis throughout the participating research communities. It will include technical support services and newly developed applications to permit both hypothesis-driven and open-ended hypothesis-generating research.

Additional Information on the Scope and Requirements of the Solicitation

1) Novel development versus integration. While some new application development will undoubtedly be necessary under this contract, this RFP is primarily intended to support the integration of the best existing applications, as well as to provide a broadly useful infrastructure upon which these applications will be disseminated. The provider of service under this solicitation:
   - may expect that the participating laboratories are familiar with existing tools in this domain and that more tools will be introduced through future NIH-sponsored procurements.
   - will be encouraged to integrate existing applications throughout their system and to take special care in forecasting and justifying where new applications will be required.
   - in pursuing their technical approaches, will be required to be creative and informed about the latest technological advances, especially in solving the unique challenges of this community, such as real-time data sharing, data security, protection of intellectual property, and data access restrictions due to human subject constraints.
   - in all aspects of the system developed here, will be expected to use formats for data representation and storage that enhance data integrity, survivability, and portability.
   - will be required to draw on the recent work of various standards-setting bodies, for example, those groups now working to establish standards for the production, maintenance, and exchange of genomic data.
   - will be encouraged to facilitate the rapid diffusion of emerging standards and to explain how this serves the interests of the community.

2) A novel system, custom data architectures, and direct technical assistance will be required to meet the needs of this research community. Specialized interdisciplinary support is required to develop and maintain a data warehouse, as well as the data

models, middleware, and query tools needed to access critical research information across various existing platforms. This support should include technical assistance to researchers in characterizing their data phenotypes and their study subjects for data archiving purposes.

To overcome the challenges associated with central data archiving in fast-moving research fields, this support should also provide advanced technology solutions to enable local data collection, as well as creative data sharing approaches. In fact, a guiding principle of this contract is that direct technical support to participating labs with data acquisition, analysis and curation is equally important as the creation of a central data archive. Advances in information technology in other domains have yielded many options for sharing, parsing, or integrating data that have yet to be tried in the life science research domain. These advances need to be delivered to NIAID-funded researchers. Novel approaches are needed to deliver these solutions to a widely distributed community, as well as to address other barriers to data integration, such as human subjects and intellectual property concerns.

3) The services to be provided should accelerate basic and applied discovery, as well as the clinical validation of various therapies by ensuring data quality, timeliness and integrity, as well as by extending the usability of these data sets to larger, evermore-heterogeneous user communities. This requires the development of a common, secure platform for the collection, storage, analysis, and dissemination of numerous heterogeneous sets of basic and clinical research data. (These data are being generated by the programs of the Division of Allergy, Immunology, & Transplantation of the National Institute of Allergy & Infectious Diseases (NIAID), see DAIT at URL: http://www.niaid.nih.gov/research/dait.htm.) As part of the requirement to enhance research, the envisioned system should demonstrate that information technology could deliver measurable benefits.

   A special sort of support is needed in order to yield measurable benefits without constraining science. This work is inspired by the recognition that this dual purpose can be achieved through the skillful deployment of recent advances in databases, knowledge representation, object-oriented programming, and data exchange protocols to existing laboratories. Support procured under this contract should provide appropriate information technology solutions, delivered according to a clearly stated and approved project management plan.

4) The envisioned system must store and disseminate information in a flexible manner, so the data models must evolve with the varied and changing needs of the research community. With this in mind, the current vision of the data warehouse includes the following components. The top level will be a frame-based representation system that supports an object-oriented organization of data with slots, facets, multiple-inheritance, and features an application programmer's interface (API) that is network accessible. The middle layer will be a translation layer that converts the knowledge representation into the underlying persistent storage mechanism in a relational database. The bottom layer will be a relational database system that is tuned to

support a high level of transactions, secure access and backup. The NIAID fully expects that a contractor suitable to perform under this solicitation will suggest novel and advanced computer-based solutions that embellish or even alter this framework in fundamental ways, but without compromising the program objectives.

5) The data model for structuring storage in this resource will contain data relating genomic information, laboratory phenotype information and clinical information. Due to the sensitivity of much of its contents, methods for guaranteeing the security of patient clinical information are essential. Thus the provider of service under this contract will be expected to demonstrate special knowledge, experience, and a creative approach to securing data while achieving the main goal of this project which is to present the most complete data set possible to the scientific public, limited only by the necessary ethical constraints, in as a rapid a manner as possible.

6) Not all of the specific projects to be supported under this contract are listed or can be predicted at this time. These projects will vary in size, complexity and duration; they range from long-term projects to special studies. These include development and maintenance of multi-institutional collaborative screening or clinical trials, biostatistical studies on various aspects of immune disease using one or more data files, development of statistical and epidemiological methodology for carrying out such research projects, pilot or feasibility screening and/or prevention trials, the conduct of epidemiological and biostatistical studies of immune disease screening and prevention. Some projects require computer science expertise in information retrieval and data analysis of existing databases which can only be carried out by the design and development of specialized software; others require the application of general purpose or existing software for data organization, maintenance and analysis. Some projects require data collection expertise in a variety of medical research settings that will necessitate the development of test instruments and coding instruction manuals, and the timely editing of data using rigorous quality control procedures; other projects require the utilization of existing data collection methods and procedures. In the majority of circumstances a high level of professional and technical expertise is required since turn-around time should be rapid, complex situations must be quickly assimilated, and accurate solutions produced using state-of-the-art technology.

7) Programs served by this contract

The NIAID is seeking bioinformatics integration support for the following major research programs. This support will extend and complement the local bioinformatics activities in each of these programs:

International Histocompatibility Working Group (IHWG, FY 2000)
The NIAID led several other ICs and the Juvenile Diabetes Research Foundation International in supporting the International Histocompatibility Working Group (IHWG), an international network of more than 200 laboratories that are collecting and sharing data on the genes of the human leukocyte antigen (HLA) gene complex; one project of the IHWG will establish an international bone marrow registry that will

facilitate more accurate matching of transplant donors to recipients. (Background information is available at <http://www.ihwg.org/>).

Immune Tolerance Network (ITN, FY 1999)
Established to evaluate promising tolerance induction approaches in 4 clinical areas: kidney transplantation, islet transplantation for type 1 diabetes, autoimmune diseases, and asthma and allergic diseases. The ITN's scientific leadership is composed of more than 70 investigators from more than 40 institutions in 9 countries. (Background information is available at http://128.218.179.235/frameset.html)

Autoimmunity Centers of Excellence (ACEs, FY 1999)
Established to conduct pilot clinical trials of tolerogenic and immunomodulatory therapies for multiple autoimmune diseases, including type 1 diabetes. These Centers support a cooperative research program of integrated basic, pre-clinical and clinical research, and conduct single and multi-site cooperative clinical trials for new immunomodulatory interventions and studies of mechanisms of action of tolerance induction. The clinical component allows the piloting of novel immune therapies for autoimmune diseases. (Background information is available at http://light.emmes.com/tolace/)

Cooperative Clinical Trails in Pediatric Renal Transplantation Program (CCTPT, FY 1999)
The NIAID initiated support of pediatric kidney transplantation clinical trials, focused on increasing the long-term survival and improving quality of life, with the establishment of the CCTPT in 1991. This multicenter clinical trial group consists of 52 pediatric transplant centers, which register and follow greater than 80% of children receiving renal allografts in the U.S. The CCTPT has successfully conducted seven (7) protocols of new treatment regimens that have changed the standard of care for children receiving kidney transplants. (Background information is available at http://camelot.emmes.com/ccp/About_Us/about_us.html)

Clinical Trials of Stem Cell Transplantation for the Treatment of Autoimmune Disease (SCT/TAD, FY 2000)
The NIAID is sponsoring clinical trials to assess the efficacy of hematopoietic stem cell transplantation for treating severe autoimmune diseases. Mechanistic studies are being performed along with the clinical trials. (Background information available at <http://www.niaid.nih.gov/ncn/concepts/c-ait6-0.htm>).

Inner-City Asthma Consortium (ICAC, FY 2002)
A new clinical research program will be established to evaluate the safety and efficacy of promising new strategies for the treatment of asthma among minority inner-city children. This new consortium of basic scientists and clinical investigators conducts clinical trials and integrated mechanistic studies of a variety of promising allergen-specific and non-specific immune-based therapies, targeting the major indoor allergens that have been identified as critical risk factors in this population.

(Background information is available at <http://www.niaid.nih.gov/ncn/concepts/c-ait10-0.htm>).

8) Estimate of Effort

To assist in proposal preparation, the Government considers the effort to be approximately 19 - 27 FTE's per year, which is a total of 133 to 189 FTE's for the seven-year effort (based on 2,080 hours per year). This estimate is furnished for the offeror's information only and is not considered restrictive for proposal purposes.

As further assistance, it is estimated that the above total labor effort is constituted as follows:

Personnel Required			
Senior or Specialized	4-6	FTE	yearly
Skilled or Experienced	12-16	FTE	yearly
Clerical or Support	3-5	FTE	yearly
TOTAL	19-27	FTE	Yearly

9) Equipment

Offerors are expected to purchase or provide hardware and software sufficient for the construction and operation of the data warehouse and all interfaces under this contract. The resulting Contractor shall assist participating programs in their own technology adoption, but shall not furnish all equipment and supplies locally, except where necessary to fulfill the data integration objectives of this project. Offerers are encouraged to propose novel methods of developing and disseminating bioinformatics solutions to participating centers and to document the benefits of their approach.

10) Subcontractors

While not required to do so, the primary Contractor may choose to team with one or more specialized organization in order to acquire special knowledge or practices that strengthens their competitiveness for this contract.

11) Meetings

For cost estimating purposes, assume the following annual meeting schedule:

	# of Attendees
Annual meeting of participating centers	75-100
Quarterly working meetings	15-25

WORK STATEMENT

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

The purposes of this contract are to: (a) provide systems analysis and planning to evaluate and quantify the data requirements of the participating programs in order to specify the data models and establish realistic performance requirements; (b) provide bioinformatics technical support to assist participating centers with data collection, storage and analysis; and, (c) design, implement and maintain a data warehouse which shall involve the full array of hardware and software elements required by participating centers, including but not limited to: (i) relational databases for data archiving, (ii) servers dedicated to specific tasks, such as web-based communications or on-line data submission, (iii) special stored records, such as personal identifiers, structured vocabularies, or ontologies, (iv) interfaces for machine-machine or human-machine data interchange, and (v) operating systems, middleware, algorithms, and programming languages to be used.

Specifically, the Contractor shall:

1. Conduct a complete systems requirements assessment.

   In performing this assessment, the Contractor shall conduct and report on an assessment of the bioinformatics requirements of all participating centers. Although many methods of requirements specification may be appropriate, the Contractor shall conduct a requirements specification that includes completion of and reporting on at least the following: (i) the determination and characterization of the novel conditions for work and information management in and between participating centers; (ii) the determination and documentation of the predominant business rules and processes that are associated with research and treatment in this community; (iii) the depiction and characterization of basic data forms and processes of data acquisition, management, and access, focusing particularly on those forms and processes that will determine a common nomenclature and tasks by which the system will be modeled; (iv) the determination of local conditions relevant to designing, testing, prototyping, and implementing software applications and information technology systems; and (v) the determination of local conditions that must be addressed in gaining acceptance of the system to be developed among end users.

2. Establish a novel curation service for new and legacy laboratory and clinical data that shall involve the following:

   a) Design and implement the architecture for a widely distributed data collection system;
   b) Facilitate community consensus on phenotype in ~ 10 diseases/distinct communities;

c) Develop and disseminate protocols to collect and archive this data;
d) Provide technical assistance in the collection, submission, and analysis of data; and,
e) Design and implement a reliable system of quality control applied to all data and media.

In achieving the above items, the Contractor shall complete the following: (i) evaluate, adopt, and extend some existing data models in this research domain of genome-focused informatics; (ii) test and extend existing interfaces and protocols for genomic data acquisition and exchange; (iii) create new data models and interfaces for the exchange of data between instruments and computers and between humans and computers; and, (iv) create new applications for the exchange, management and quality control of data to be shared, archived and curated.

The Contractor shall make use of extensive modeling in order to define, implement, and maintain a database that models essential aspects of the immune phenomena of interest to participating researchers.

The Contractor shall allow for the integration of legacy data from relevant instruments and archives (both public and private), the future acquisition of high-quality data, and the computer-based analysis of those data.

Successful completion of the above shall require the Contractor to complete at least the following: (i) the design, implementation and maintenance of a scaleable architecture for representing, acquiring, and storing genomic data of many classes, including but not limited to genetic, cellular, molecular, and clinical; (ii) the rapid dissemination of software for the capture, analysis, query, and storage of genomic data; (iii) the linkage to other relevant existing data sources and support of the integration and analysis of those data sets; and (iv) the enabling of researchers to share data and analytical tools more readily.

3. Lead system and data integration for diverse sets of genomic, clinical, and other data that shall involve the following:

a) Design and implement a widely distributed on-line scientific data query system;
b) Develop machine-usable knowledge representations of research and disease phenotype;
c) Develop and implement a plan to ensure the usability, interoperability, survivability, and portability of all data sets;
d) Develop a data base translation protocol to integrate and query across several archives;
e) Develop interfaces and procedures for lab data entry by machine or human users (e.g. LIMS); and,
f) Disseminate information and train participating labs on the system and its use procedures.

4. Provide ongoing technical assistance to each of the participating labs with the local analysis and curation of their data. This will involve the following:

   a) Providing ongoing technical assistance in the collection, submission, and accessing of data relevant to the common research interests of participating labs. This technical assistance shall extend to methodological assistance in biostatistics and research design only where it is critical to the quality and utility of data used in this network;
   b) advising on the selection and use of software and hardware for data collection and analysis;
   c) providing information and software to assist laboratories in the collection and normalization of data;
   d) providing assistance in technology selection to see that tools adopted locally for data capture and analysis are of the best quality;
   e) providing assistance with phenotype development to see that the local nomenclature and data representations are coordinated with those used centrally; and
   f) training bioinformatics professionals at participating labs in order to see that all applications and services are fully understood at the local labs.

5. Develop new software applications to support databasing and data analysis that shall involve the following:

   a) Develop new and novel metadata and middleware;
   b) Where necessary and agreed to by the Project Officer, develop advanced intelligence applications for data analysis;
   c) Develop secure archival applications in clinical trials informatics;
   d) Develop special applications for data collection and management; and,
   e) Develop special data collection applications for machine and human interfaces.

   The Contractor shall develop and disseminate applications that enable scientists working independently in participating programs to generate, normalize, archive, and exchange data of all types easily and without risk of corruption. The Contractor shall draw on the latest advances in software engineering and computer sciences and translate those advances into practical tools that are easily used by the target users in this project.

   The Contractor shall develop, acquire, and disseminate applications as appropriate that address what NIAID has determined to be the most pressing needs of participating centers which are: (i) improved processes and interfaces (human-machine and machine-machine) for data submission and exchange, (ii) common standards of knowledge representation to enable cross-platform portability of research data, (iii) translation middleware to extend the usability of large legacy data sets, (iv) linking software, as applied to navigation, annotation, or document version accessing, and (v) controlled access and data sharing protocols to protect records under complex human subjects or intellectual property constraints.

6. Manage and maintain a system of data collection and archiving that shall involve the following:

    a) Develop uniform, intelligent web-based interfaces for remote data entry by human users.
    b) Assist participating labs with submission of normalized, high quality data.
    c) Receive data from participating centers and insure the quality and integrity of those data. The exact nature of the data are to be determined in the requirements assessment, but are expected to include genotype data, DNA marker names, allele sizes in base pairs and corresponding frequencies, and relative map distances for each marker. In addition, the Contractor shall obtain from all participating laboratories results from sequence and mutation analyses and any other genetic analyses that may become available.
    d) Create an electronic database containing all available scientific data for each subject, including but not limited to, clinical, diagnostic and pedigree information. This shall include all genotyping information, as well as DNA marker names, allele sizes in base pairs and corresponding frequencies, and relative map distances for each marker. All such genotypic information shall be maintained in electronic databases in a format that permits rapid and efficient production of files for distribution. The Contractor shall carefully verify all data in collaboration with the participating laboratories on the grants or contracts under which the data were collected.
    e) Specify and disseminate data standards for future data collection and analysis.
    f) Integrate system and operational changes according to user needs and technological advances.
    g) Develop/implement a long-range plan for the long-term maintenance and survival of the data.

    Distribute electronic files of clinical, diagnostic, genotypic, and pedigree structure data only with the approval of the NIAID, and in accordance with current state or federal laboratory procedures assuring appropriate usage of genetic material.

    With regard to the data intended for central archiving, the Contractor shall not use data for any purpose, other than that specified in the contract, without written approval of the NIAID Project Officer.

7. Develop and implement a system for monitoring security and system performance.

    a) Develop a program and needed applications for monitoring use of the system;
    b) Develop and implement a plan to protect data derived from human subjects;
    c) Test the system to ensure that it is performing according to requirements;
    d) Report on and repair any potential problems with the system;
    e) Inform and train users in the security procedures of the system; and,
    f) Develop, implement, and maintain security requirements, including:

1) An Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); and, the Continuity of Operations Plan (COOP)(also known as the Contingency Plan);

2) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls; and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting purposes;

3) The preparation and submission, for Project Officer approval, of an RA following the guidance given in DHHS AISSP Handbook (<http://irm.cit.nih.gov/policy/aissp.html>). The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements;

4) The preparation and submission of an annual SSP, following the instruction in OMB Bulletin 90-08, for review and approval by the Project Officer and the NIH SSO (<http://irm.cit.nih.gov/itmra/omb90-08.html>);

5) The development and maintenance of an up-to-date COOP following the guidance in DHHS AISSP Handbook (<http://irm.cit.nih.gov/policy/aissp.html>). At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months;

6) Plans, procedures, and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from clinical and mechanistic study sites. This includes data integrity and security during electronic transmission, or during transit from the sites to the BISC if non-electronic data transmission is used. All patient identifiable data is subject to the Privacy Act and DHHS regulations; and

7) Provision for the appropriate labeling, storage, handling, and disposal of sensitive or controlled data, media, and output.

8. Monitor performance and plan for future activities.

a) For items 1. - 5. above, specify solutions to be built and metrics for determining when requirements are met. Specific performance shall be derived from (i) a knowledge of best practice in information technology performance measurement;

(ii) an in-depth understanding of the critical challenges of laboratory and clinical medicine; and (iii) close communication with the NIAID Project Officer and participating labs.

b) Determine the costs and benefits for continuing the BISC in its present and future modes of operation.

c) Monitoring and planning shall be done through close communication with the NIAID Project Officer and the leadership of participating centers. In the preparation of these plans, the Contractor shall:
   1) identify and characterize additional bioinformatics needs that can be served by the BISC;
   2) identify, measure and explain barriers and benefits already achieved by the work and services of the BISC;
   3) propose new functionality and services to be developed to serve the needs of the BISC community; and,
   4) propose a plan for the future development of the BISC as well as the maintenance of its data and applications.

9. Communicate regularly with the NIAID Project Officer and leadership of participating centers throughout the life of the project.

   a) Develop a detailed communications strategy that:
      1) captures their scientific inputs relevant to system and software design;
      2) establishes mechanisms for ongoing input into subsequent versions of the system;
      3) allows for rapid dissemination of new methods and tools developed under this contract (including training); and,
      4) establishes a way for end-user feedback to be readily integrated into Contractor activities so that the overall performance of the system is continually improved.

   b) Collaborate with the NIAID Project Officer and the leadership of participating labs to address key policy issues including, but not limited to, (1) data access and release; (2) standard nomenclature; (3) data submission and dissemination formats; (4) data security policy; and, (5) intellectual property.

   c) Conduct quarterly and annual working meetings, including all costs associated with travel for BISC staff and the leadership of participating labs. The participants at these meetings will include BISC staff, the leadership of participating labs, and NIAID program staff.

10. Ensure an orderly and timely transfer of all data, information, and contract-related materials to a successor contractor or the Government. Six months prior to the contract completion date, a transition plan shall be submitted to the Project Officer for approval.

[END OF STATEMENT OF WORK]

Reminder: Please send comments to Cyndie Cotter, Contracting Officer

DELIVERABLES AND REPORTING REQUIREMENTS

As a mission-critical initiative, this seven-year project will be closely monitored for its entire duration. The initial three years, however, will be critical to design and implementation. It is expected that the project should be fully implemented and demonstrate measurable results within the initial 30 months. The NIAID has made a long-term commitment to the work and services described in this RFP, however, various unforeseen changes could necessitate a change in direction for this project. After three years, therefore, it is anticipated that the NIAID will evaluate the project and make a "go/no-go" decision about terms and conditions of its continuation. At this time, the NIAID will also determine whether any major changes to the project design or contracting arrangements are required. The NIAID reserves the right to terminate, re-compete, or negotiate a modification to the contract at this time. The NIAID also reserves the right to continue or discontinue this project based on the NIAID's own assessment of what best serves the interests of its research community. In formulating its decision, the NIAID will evaluate the performance of the incumbent Contractor (looking especially for measurable indicators of success in serving the research needs of the research community) and evaluating recommendations for continuation of the project as well as other interested and informed parties.

Over the course of the contract, the Contractor shall deliver each of the items listed below. The schedule for delivery for these items (approximated here) is subject to modification based on agreement by the NIAID Project Officer and the Contractor. The completeness and acceptability of all deliverables will be determined by the NIAID Project Officer at his or her sole discretion and in consultation with an advisory body comprised of representatives from participating centers.

Year One

(a) Requirements assessment (approximate due date: project month 4);
(b) Systems architecture and build-out plan (approximate due date: project month 5). This shall be a modification of the plan presented in the original proposal based on information gathered through the requirements assessment. The build-out plan shall include a detailed work breakdown structure and staffing plan;
(c) Bioinformatics service plan. (approximate due date: project month 6) A detailed plan for providing bioinformatics support to participating centers. This shall include a plan for monitoring and assessing Contractor performance as determined by the needs and expectations of end-users;
(d) Prototypes of all data models, middleware, and interfaces necessary for data collection, normalization, analysis, and archiving. (approximate due date: project month 7);
(e) Curriculum for all training to be offered as part of the bioinformatics service plan (approximate due date: project month 8);
(f) Annual report and requirements update (approximate due date: date project month 10). This Annual report shall include the annual Automated Information System Security Report, which includes the Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the

Risk Analysis (RA); and the Continuity of Operations Plan (COOP) (also known as the Contingency Plan).

Year Two

(a) Demonstration of a fully operable data warehouse including interfaces for data collection, data models, and ontologies or structured vocabularies, as well as initial documentation for all hardware and software. (approximate due date: project month 18);
(b) Proof of a fully operational bioinformatics support service including a reckoning of the level and types of service utilization. (approximate due date: project month 18);
(c) Report of an annual meeting of end-users detailing the support levels and functionality they require. (approximate due date: project month 20) ;
(d) Demonstration of tested schemes for (i) data submission at all community-agreed interfaces; (ii) data normalization; (iii) data curation; (iv) data sharing; and (v) data comparison;
(e) Annual report and requirements update (approximate due date: project month 22). This report shall explain benefits delivered by the data warehouse and technical support work. It shall discuss any barriers to implementation and how they have been addressed. It shall discuss the current and needed functions of the platform based on a thorough understanding of end-user requirements. In addition, it shall include the annual Automated Information System Security Report (described above in Year one, item (f))

Years Three through Six

(a) An Annual Report and Continuation Plan shall be submitted by the Contractor in a timely fashion. (approximate due date: project month 33, and every 12 months thereafter until contract completion). This annual report shall include the annual Automated Information System Security Report (described above);
(b) Copies of all project work products produced up to that date. (approximate due date: project month 35, and every 12 months thereafter until contract completion).

Year Seven

(a) A final report shall be submitted by the Contractor in a timely fashion. (approximate due date: project month 80);
(b) All project work products produced up to that date. (approximate due date: project month 82). When instructed by the NIAID Project Officer, the Contractor shall be prepared to deliver to the Government (i) the data model and any accompanying documentation; (ii) the hardware and software comprising the data warehouse, including all accompanying documentation; and (iii) any software applications that have been developed under this contract.

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PROPOSED EVALUATION CRITERIA

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: Technical, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

The demonstrated evidence of capability should include current and/or past related work experience, activities for related requirements, and the qualifications, availability, and experience of the professional and technical personnel necessary to perform contract requirements. Proposals will be evaluated based on the following factors:

WEIGHT

A. TECHNICAL APPROACH **Points: 50**

The proposal should be evaluated based on the Offeror's documented ability to:

- Conduct a complete systems requirement assessment;
- Establish and maintain a curation service for new and legacy laboratory and clinical data;
- Lead large-scale projects for systems design and data integration projects in a life sciences research and clinical setting; including the demonstrated ability to gain consensus for a scientific rationale or an engineering approach relevant to the work statement;

- Provide ongoing technical assistance to a large, heterogeneous research community, including the local analysis and curation of data;

- Develop new software applications, especially where the analysis, storage, and exchange of scientific data are concerned; including the demonstrated ability to ensure the usability, interoperability, survivability, and portability of all data sets;

- Manage and maintain a system for data collection, archiving, and redistribution in a scientific research setting. This includes the ability to consistently work in a coordinated and efficient manner with subcontractors and participating centers over the life of the project;

- Develop and implement a system for assessing requirements and monitoring system performance, including system security. This includes evaluation of the Offeror's Information Technology (IT) Security Plan;

- Develop a system to serve the data analysis and management requirements of a large, heterogeneous, and widely distributed research community; including the demonstrated ability to communicate findings, methods, outcomes, and performance metrics with participating labs and program staff;

- Develop and implement a program to communicate regularly with the NIAID project officer and leadership of participating centers throughout the life of the project; and,

- Provide an adequate and feasible plan for sustaining or transferring this activity to a successor contractor or the Government.

B. PERSONNEL **Points: 30**

The Offeror should document relevant training, qualifications, expertise, experience, education, competence, and availability to perform the requirements of the work statement. The Offeror should provide evidence of the quality of the professional team proposed to undertake the work solicited in the work statement. That evidence of ability should include the demonstration of previous experience doing similar complex projects, as evidenced in documentation of previous relevant assignments and, where appropriate, publications.

1. Basic and Clinical Life Sciences Research
   The Offeror's proposed personnel should:
   a) possess complete knowledge of clinical and basic biomedical research and documented ability to translate that knowledge into information systems which improve life science data acquisition, analysis and dissemination;
   b) possess superior knowledge of biostatistics and all the life sciences relevant to immunology research;

c) demonstrate excellence in laboratory automation, including knowledge of laboratory information management systems (LIMS) and all other computer-based methods of data collection and management; and,
d) possess complete and practical understanding of the policy matters affecting the protection of human subjects in life science research as they pertain both to tissue and information.

2. Computer Science, Systems Integration and Engineering
The Offeror's proposed personnel should:
a) demonstrate knowledge of artificial intelligence and other computer-based algorithmic approaches to querying and analyzing data;
b) demonstrate complete knowledge of the bioinformatics support required to generate, analyze, and curate life science research data of all types; and,
c) demonstrate complete knowledge of systems integration and project management methods.

C. FACILITIES **Points: 20**

The Offeror should demonstrate:

1. the availability and adequacy of the offeror's proposed facilities;

2. access to and knowledge of all equipment and other resources necessary for performance of the contract; and,

3. plans and capacity for material and data distribution, including but not limited to telecommunications infrastructure and server capacity, established methods for avoiding data loss and corruption, as well as tracking errors in handling of all materials.

TOTAL POINTS **100**

D. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTORS (SUBJECTIVE ASSESSMENT)

Evaluation of the Offeror's Small Disadvantaged Business Participation Plan will be based on information obtained from the Plan provided by the offeror (with their business proposal), the realism of the proposal, other relevant information obtained from named SDB concerns, and any information supplied by the offeror concerning problems encountered in SDB participation.

Evaluation of SDB Participation Plans will be a subjective assessment based on a consideration of all relevant facts and circumstances. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor. The assessment of the Offeror's SDB Participation Plan will be used as a means of evaluating the relative capability and commitment of the offeror and the other

competitors. Thus, an offeror with an exceptional record of participation with SDB concerns may receive a more favorable evaluation than another, whose record is acceptable, even though both may have acceptable technical proposals.

SDB Participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB participation Plan will be influential in determining the relative merits of the Offeror's proposal and in selecting the offeror whose proposal is considered most advantageous to the Government.

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